

REMARKS

In the official action, the Examiner objects to the drawings and the specification, and rejects the claims as obvious, principally over the Mayer patent.

Drawings:

The applicant respectfully disagrees regarding the drawings objection. The item 52 is identified by number in Fig. 5, where the entire element 52 is shown. At the bottom of page 10 of the specification, the item 52 is described as a flexible, remote force-applying device. Therefore, no correction to the drawings is believed necessary.

Specification:

Regarding the specification, corrections have been made to address all of the objections of merit. However, regarding the element 52, no change is believed necessary, the wording used being well within the permitted latitude in drafting patent applications. Page 10 describes the device 52 as a "flexible, remote force-applying device 52". On page 11 the same device is referred to in shorthand manner as "the remote device 52". It is the only remote device 52 referenced or described in the application thus far at page 11, and there is no possibility of confusion, particularly since the reference number 52 was

included in both cases. There is no requirement that a term as first used for a particular element in a patent application be repeatedly referred to by its full name in every subsequent appearance. Patents very commonly refer to a "apparatus 50" or a "machine 10" after an earlier introduction of that element by a longer and more descriptive name. Thus, it is submitted no ambiguity in this regard, with no need for any change.

Title:

The title has been changed as requested.

Prior Art Rejections:

The Examiner rejected all of the claims under Section 103 over the Mayer patent. That rejection is respectfully traversed.

In a rather lengthy statement of reasons for rejection, the Examiner recites the prior art elements of the claims, then recites the novel elements of the claims, i.e. a flexible cable release device and its connection to and function with the clip applier, or a flexible remote force-transmitting device, more broadly. The Examiner acknowledges that the prior art clip applier device does not contemplate a remote application, via any form of remote force-transmitting device, whether fluid operated or cable operated.

However, the Examiner cites the Mayer patent as somehow

bridging the gap and showing obvious the inclusion of the remote force-transmitting device as claimed and as understood in light of the present specification and drawings.

Modification of the prior art clip applying device is neither contemplated in the device itself or in the Mayer patent, and the Mayer patent provides absolutely no suggestion or motivation to make such a modification or combination, nor the features which would be needed to make that modification.

The Mayer patent describes a very complicated system for synchronizing to the heartbeat so that sutures or clips can be applied to the beating heart. The actuation of these sutures or clips is through a device described in great detail. Mayer does not describe a remotely operated suture applying device but rather a clip applying device having a slidable finger pad 37 attached to the barrel or housing of the clip applier itself.

The essence of the present invention, and of the claims of the application, is the modification of the direct force application in the prior art clip applier, by use of a remotely activated force applying device. The fact is that the Mayer patent device could well be improved by a remotely operated force applying device as in the present invention, which would replace the sliding finger pad motion shown on the barrel of the applicator in the Mayer patent.

Even though it seems clear in original claims 1 and 3 that

the actuator end of the cable release or remote force-applying device was positioned at a remote location from the clip applier (especially made clear in the "whereby" clauses), both claims 1 and 3 are now amended to add "remote from the clip applier" to characterize the location of the remote end of the flexible device.

Clearly Mayer teaches the opposite, with the finger pad attached directly to the barrel of the clip applier and thus incapable of actuating the clip applier without motion from the finger transferred through the barrel to the clip end.

Several assumptions made by the Examiner are actually untrue. At the top of page 7 of the action, the Examiner refers to the Mayer device as being used under the microscope. The Mayer device, however, is not a microsurgical device and is not used under the microscope. Further, at page 7 line 2 of the action, the Examiner states that the Mayer device would apply force at the remote end of the cable release device "avoiding any movement of the tip at the instant of the clip application", also not in fact the case. The cable release device 37 on the Mayer clip applier is actually operated by the surgeon and, as noted above, it cannot avoid any movement at the tip because of the location of the finger pad slide actuator.

Further, at the bottom of page 7, the Examiner quotes the instant patent application, apparently attributing this to Mayer.

Mayer does not describe what the Examiner recites at lines 19-22 of page 7 of the action. This is also true of page 8, lines 1-4.

Thus, it is submitted that the Examiner's conclusion beginning at page 8 line 7 of the action, is unsupportable. The Examiner concludes that it would have been obvious to modify the prior art surgical clip applier as described in the present specification to provide a thumb actuator and cables as taught by Mayer for the purpose of having an actuation button remote from the handle, thus providing more stability to the system. This begs the question; Mayer recognizes no such purpose or motivation. The conclusion is unsupportable because Mayer does not teach the remote location of the actuator and does not teach isolation of the clip applier tip from the motion or vibration associated with the actuation of the device by the surgeon or assistant. Mayer actually teaches the opposite.

Although Mayer does incidentally show a cable release, it is not used in the way described in the present claims and does not suggest such a use at a remote location. Instead, Mayer teaches mounting a finger pad slide device directly on the barrel of the clip applier.

Further, the dependent claims add further patentable subject matter, despite the Examiner's statements essentially that these claims recite inherently obvious elements. For example, claim 4 recites the separability of the force transmitting device, via a

threaded fitting at the proximal end, with a mating thread at the tail end of the clip applier's handle. This feature, relating to modularity, is important for reasons described in the specification, one of the pieces being disposable, and thus utility is added via the severability of the two components. The Examiner must present prior art to show obviousness, not merely state a feature is inherently obvious. The undersigned attorney has reviewed cases from time to time regarding integral structures and non-integral structures and the patentability thereof, but these cases are always specific to their particular facts. No case is ever held that the modular separability of two components that screw together is unpatentable as a matter of law. Besides, in this case there is no "formerly integral structure" that would correspond to this invention (and which, incidentally, would be covered by claim 3). Claim 3 in particular does not require that the flexible force transmitting device be separable from the clip applier, and would cover an integral device, whereas claim 4 does recite this separability.

Claims 9-11 are method claims, and these claims very clearly distinguish over the cited prior art and over the acknowledged prior art. Claim 9 recites that the depressing of the actuator is not performed by the hand holding the handle of the clip applier and recites that the depressing of the actuator is at the distal end of the flexible device. This clearly distinguishes

from what is plainly taught in the Mayer patent: that the finger pad slide actuator is mounted on the clip applier barrel itself. Claims 10 and 11 add further method steps, reciting that a different person from the person holding the clip applier depresses the actuator; and that a foot pedal is used, respectively. These features and steps are far afield from what is plainly stated, shown and taught in the Mayer patent.

It is therefore respectfully submitted that all of claims 1-11, particularly with the amendments to claims 1 and 3, are clearly distinct from the prior art and should be allowed. However, the Examiner is invited to telephone the undersigned attorney if any issue remains.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Thomas M. Freiburger', with a stylized flourish extending from the bottom right.

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